

**Testimony of Caroline Smith DeWaal  
Director of Food Safety  
before the  
Senate Committee on Commerce, Science and Transportation  
Hearing on "Mad Cow Disease: Are Our Precautions Adequate?"**

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My name is Caroline Smith DeWaal and I am director of food safety for the Center for Science in the Public Interest (CSPI). CSPI is a non-profit organization based in Washington, DC. Since 1971, CSPI has been working to improve the public's health, largely through its work on nutrition, food-safety and alcohol issues. CSPI is supported primarily by 850,000 subscribers to its Nutrition Action Healthletter, the largest circulation health newsletter in North America.

Thank you for inviting us to present testimony today on "Mad Cow Disease: Are Our Precautions Adequate?" Thankfully, for both American cattle producers and the public, no case of bovine spongiform encephalopathy (BSE), the scientific name, has ever been identified in U.S. cattle. However, as the outbreak of foot and mouth disease in Europe has recently reminded U.S., the absence of disease should not be an excuse for complacency.

To USDA's great credit, in the late 1980's, it instituted a critical first line of defense to prevent BSE from infecting U.S. cattle herds. Before the human health consequences were even known, to protect U.S. cattle herds, the USDA banned the importation of ruminants (cattle, sheep, and goats) and



ruminant by-products from the United Kingdom and other countries where BSE had been found.<sup>1</sup> In 1997, the ban was extended to cover all of Europe. Clearly the U.S. government has been very proactive to prevent mad cow disease from infecting our animal population. This precaution has paid off, both for consumers and for the meat industry.

The meat industry also deserves credit. Up until 1998, many slaughterhouses stunned their cattle with an air-injection rifle before killing them.<sup>2</sup> But then CSPI disclosed several studies in Nutrition Action Healthletter showing that the explosive blast of air could scatter brain tissue throughout the carcass. In cows with BSE, brain tissue is highly infectious. First, the meat industry did a study that confirmed the risk of spreading brain tissue using this type of stunning equipment, then companies voluntarily changed to safer devices. According to an industry representative, no one is even manufacturing the air-injection stunning equipment in the U.S. any more.<sup>3</sup>

While these steps have been very important, there is more that must be done in order to protect American consumers from the crisis in confidence that has emerged in Europe in recent years.

## **TSEs are Devastating Diseases**

BSE is one of a family of neurologic diseases called transmissible spongiform encephalopathies (TSEs), which are characterized by a relatively long incubation period, short duration of clinical signs,

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<sup>1</sup> U.S. Department of Agriculture, "U.S.DA Actions to Prevent Bovine Spongiform Encephalopathy (BSE)," April 1998, available at <<http://www.aphis.U.S.da.gov/oa/bse/bsechron.html>>Internet.

<sup>2</sup> Schardt, David and Schmidt, Stephen, "Mad about BSE", Nutrition Action Healthletter, Vol. 24, No. 6, July/August 1997.

<sup>3</sup> Personal conversation with AMI Representative.

and a 100% mortality rate.<sup>4</sup> TSEs have been documented in a wide number of species, including sheep (scrapie), cattle (BSE), humans (Creutzfeldt-Jakob disease or CJD), deer, mink, cats, and others.

Many cases of TSEs, including 90% of CJD cases, are sporadic, which means that the disease can show up in an individual with no apparent cause.<sup>5</sup> The disease is also infectious. TSEs can be spread mainly through consumption of infectious tissue. TSEs can be transmitted from one species to another, although significant barriers exist to prevent this.

Sometime in the late 1980s or early 1990s, BSE jumped the species barrier between cattle and humans during the British BSE epidemic in cattle.<sup>6</sup> Consumption of BSE-infected cattle has been linked to the development of a new variant of CJD in humans. Unlike the sporadic form of the disease, which seldom strikes those under age 50, the variant Creutzfeldt-Jakob Disease (vCJD) shows up in young men and women. It often starts with leg pain and difficulty walking but eventually leads to a progressive brain damage that leaves its victims hallucinating, unable to see, speak, or feed themselves, and, within a year or two, dead.

In 1996, vCJD killed ten people in Europe; last year it killed 27.<sup>7</sup> In all, nearly 100 people have died from the disease in Europe.<sup>8</sup> No one knows how many more are already infected and will

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<sup>4</sup> U. S. Department of Health and Human Services, “FDA Proposes Precautionary Ban Against Ruminant-to-Ruminant Feedings,” HHS News, P97-1, January 2, 1997, p. 1.

<sup>5</sup> The World Health Organization, “Bovine Spongiform Encephalopathy (BSE),” Fact Sheet No. 113, (Revised), December 2000, p. 3, available at <<http://www.who.int/inf-fs/en/fact113.html>>Internet.

<sup>6</sup> *Id.*

<sup>7</sup> UK Department of Health. “Monthly Creutzfeld-Jakob Disease Statistics,” March 5, 2001, p.1., available at <<http://www.doh.gov.uk/cjd/stats/mar01.htm>>Internet.

<sup>8</sup> *Id.*

develop vCJD, which can take five to ten years to emerge. BSE in cows and vCJD in humans are both caused by prions—virtually indestructible proteins that have the remarkable ability to induce other proteins to become deformed.

## **Tracking BSE in U.S. Cattle**

U.S. law currently requires that a federal veterinarian check every cow or steer before it is slaughtered. If a cow appears to be suffering from a central nervous system disorder, it is segregated and slaughtered separately. If a cow is suspected of having BSE, its meat is held while its brain is sent off for testing in an Animal Plant and Health Inspection Service (APHIS) laboratory. Currently, the brains of about 1,000 suspicious cattle are tested each year by the government. But in 12,000 tests conducted since 1990, not one has been positive.<sup>9</sup>

In addition to this government-run system, every veterinarian and university researcher in the U.S. knows that being the first to identify a case of mad cow disease will bring a certain prominence that can be helpful in getting future research funded. If the disease was present in the U.S. cattle population, it would likely show up in the dairy cattle population first, but no cases have been documented. While the absence of a positive doesn't prove that BSE isn't here, it does increase our level of confidence. If it is here at all, BSE is very rare.

But it may take only one infected cow to spread the disease. Since 1996, when BSE was first identified as a human health hazard, the U.S. government has tried to create “firewalls” to prevent BSE

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<sup>9</sup> U.S. Department of Agriculture, Animal and Plant Health Inspection Service, “BSE Surveillance,” p. 5., available at <<http://www.aphis.U.S.da.gov/oa/bse/bsesurvey.html>>Internet.

from gaining a foothold here. One firewall protects cattle from BSE; the other prevents people from getting sick if the first part fails. Currently both parts have holes in them.

## **Protecting U.S. Cattle from BSE**

The first firewall was USDA's import ban covering cattle from countries with BSE. In 1997, the Food and Drug Administration (FDA) erected a second firewall by prohibiting cattle operations from feeding meat-and-bone meal supplements made from rendered cows or sheep to cows or sheep. However, several gaps in the feed ban need to be filled.

The banned meat-and-bonemeal can still be fed to pigs and poultry. While cows get BSE and sheep get a BSE-like disease called scrapie, there is no evidence that pigs and poultry get BSE-like diseases from their food. However, processing ruminants into animal feed opens the door for banned material to inadvertently be fed to cattle.

Recent events have shown that this is fact happening. In a survey of feed mills and renderers, FDA found that more than 20 percent had no system in place to prevent commingling and cross-contamination, as required by the feed ban. And 85 feed plants of over 400 surveyed didn't label their feed with a warning about which animals it was (and, more importantly, wasn't) intended for.<sup>10</sup>

The problem made headlines in January, when a Texas feedlot inadvertently fed meat-and-bone meal intended for pigs and poultry to more than 1,200 cattle.<sup>11</sup> A clerk at Purina Mills in St. Louis had

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<sup>10</sup> General Accounting Office. Report to the Honorable Richard J. Durbin, United States Senate. "Food Safety Controls Can Be Strengthened to Reduce the Risk of Disease Linked to Unsafe Animal Feed," September 2000.

<sup>11</sup> "Texas Cattle are Quarantined to Determine Mad-Cow Risk," New York Times, January 27, 2001, p. A8.

mistakenly mixed the pig-and-poultry supplement into the company's cattle feed. Although the meal was produced in the U.S. from BSE-free cattle, Purina Mills said it would purchase the animals to keep their meat out of the food supply.<sup>12</sup> If further breaches like this occur, FDA should consider banning the use of meat-and-bone meal in all types of animal feed.

Unless Congress gives FDA additional inspection resources, violations of the feed ban are certain to occur. With just a few hundred inspectors to examine the safety of over 57,000 food manufacturers and warehouses in the U.S., feed mill inspections are a relatively rare event. FDA has only a handful of inspectors regularly tasked to feed mills to check for compliance with its requirements. Although feed mills and renderers are trying to remedy the situation by setting up third-party verification systems, that is not a substitute for government enforcement of the law.

In addition, FDA needs to strengthen enforcement of the feed ban by using modern scientific tests to ensure that companies are complying. When FDA developed the feed ban, it did not require companies to utilize a sampling system to check that the feed is free of prohibited material. This testing is critical to effectively enforce the feed ban. The British government uses a test that differentiates mammalian from non-mammalian tissues to enforce their mammalian-to-ruminant feed ban,<sup>13</sup> and a similar test should be used in the United States to enforce the feed ban. Otherwise, enforcement largely depends on a paper trail.

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<sup>12</sup> Blakeslee, Sandra. "Agency Clears Texas Cattle in Quarantine," New York Times, January 31, 2001, p. A18.

<sup>13</sup> Telephone conversation with Michael Hansen of Consumers' Union, April 28, 1997.

These regulatory holes in the firewall protecting cattle feed are troubling. They also support the need for another level of protection to safeguard the human food supply. For the last five years, CSPI has urged USDA to erect another firewall to protect consumers from the possibility that infectious prions could enter the meat supply through advanced meat recovery systems.

## **Protecting U.S. Consumers from BSE**

Advanced meat recovery systems that use infected parts of cattle with BSE could transmit the disease to humans. These machines take bones with attached meat and put them through a device that removes the meat from the bone. They claim to detach the meat without crushing, pulverizing or grinding the bone itself. According to the Food Safety and Inspection Service (FSIS), bones must emerge from these machines essentially intact and in natural conformation so that they are recognizable, i.e., comparable to those resulting from hand-deboning. Advanced meat recovery systems produce a product that can be called “meat” under current government requirements.<sup>14</sup>

If spinal cord is attached to the spinal column that enters these machines, it is bound to be incorporated into the meat that is produced.<sup>15</sup> Spinal cords from cows with BSE are highly infectious. Advanced meat recovery systems provide the single best opportunity for BSE-infected material to enter the food supply today. And this meat is used in several staples of the American diet, like hot dogs,

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<sup>14</sup> U.S. Department of Agriculture, Food Safety and Inspection Service, Proposed Rule, Meat Produced by Advanced Meat/Bone Separation Machinery and Recovery Systems, 9 CFR Parts 301, 318, and 320, Docket No. 96-027P.

<sup>15</sup> B.P. Demos and R.W. Mandigo, “Chemistry and Composition of Mechanically Recovered Beef Neck Bone Lean,” Journal Series, Nebraska Agricultural Research Division, Paper No. 10997, p. 64-65.

hamburgers and sausages. In fact, the USDA says that hot dogs and sausages can contain up to 20 percent mechanically-separated beef or pork. (An even riskier process is used to produce mechanically separated meat, one that allows the spinal cord to become part of the meat produced. This practice should clearly be banned.)

The parts of the cattle known to carry the infectious agent that can cause BSE include the spinal cord, brain and retina.<sup>16</sup> Great Britain has banned “specified bovine offal” from the human food chain, including the brain, spinal cord, tonsils, thymus, spleen and intestines. To minimize the risk of BSE entering the human food supply, it is critically important that FSIS place restrictions on the use of those cattle parts in mechanical meat recovery systems.

In 1997, following a request by the Center for Science in the Public Interest,<sup>17</sup> the USDA directed its employees to periodically check the spinal columns going into the advanced meat recovery systems to ensure that plant employees are “completely removing spinal cord from neck and/or back bones before the bones enter the [AMR] system.”<sup>18</sup> In addition, inspectors were instructed to sample product if they thought plant employees were not adequately removing the spinal cord.

Evidence to date suggests that these inspections are rarely performed, in part because the USDA believes they are not food safety violations. Between 1998 and 2000, fewer than 60 samples of

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<sup>16</sup> European Commission Listing of Specified Risk Materials: a scheme for assessing relative risks to man. Opinion of the Scientific Steering Committee adopted on 9 December 1997 (Re-edited version adopted by the Scientific Steering Committee during its Third Plenary Session of 22-23 January 1998), available at <[http://europa.eu.int/comm/food/fs/sc/ssc/out22\\_en.html](http://europa.eu.int/comm/food/fs/sc/ssc/out22_en.html)>Internet.

<sup>17</sup> Center for Science in the Public Interest, Letter to Secretary Glickman and Administrator Billy, January 7, 1997.

<sup>18</sup> U.S. Department of Agriculture, FSIS Directive 7160.2, “Meat” Prepared using Advanced Mechanical Meat/Bone Separation Machinery and Meat Recovery Systems, 1997.



meat were analyzed under this directive. This is a pitifully small number, considering that 45.3 million pounds of beef was produced by A.M.R. systems in just one of those years. Two of those samples were positive for central nervous system tissue, and peripheral nerve tissue was found in other samples as well.

Clearly, this system is not adequate to protect consumers if BSE occurred in U.S. cattle. Therefore, CSPI will petition USDA next month to ban the spinal column and neck bones from cattle in advanced meat recovery systems. We believe the horrifying human illness justifies that additional precaution. Europe has opted for a more radical solution. This year, the European Union outlawed the production of all mechanically-separated meat that comes from cows or sheep.<sup>19</sup>

In addition, USDA should ban the use in human food of all bovine offal that has been identified as containing the infectious agent for BSE, including but not limited to the brain, retina, spinal cord, spleen, thymus, nostrils, and intestines. Britain has also banned “beef on the bone,” for example, T-bone steaks. Such a ban would mirror the recommendation of the World Health Organization, as well as the ban implemented by the British government.<sup>20</sup>

## **Other FDA-Regulated Products**

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<sup>19</sup> The European Commission, Health and Consumer Protection Directorate-General Press Release, “Commission approves further protection measures against BSE,” Brussels, February 7, 2001, p. 3, available at <[http://europa.eu.int/comm/dgs/health\\_consumer/library/press/press106\\_en.html](http://europa.eu.int/comm/dgs/health_consumer/library/press/press106_en.html)>Internet.

<sup>20</sup> WHO Factsheet 113.

The Food and Drug Administration (FDA) has responsibility for assuring the safety of a number of products that could transmit BSE from cattle to humans. Here is a brief review of some matters regulated by FDA:

C Gelatin is an animal protein that comes from the hides and bones of cows and pigs. It's what makes Jell-O® gel and gummy bears soft and pliable. It's used as a thickener in some yogurt, ice creams, and other foods. And it's in the capsules, gel caps, and coatings of many over-the-counter supplements and prescription drugs.

Is gelatin infectious if it's made from animals that have mad cow disease? Probably not. Skin and hides don't seem to carry any risk, while bones have a "low infectivity" (because they contain bone marrow), according to the World Health Organization. Few, if any, BSE experts see a problem.

Even so, in 1992, the FDA asked gelatin manufacturers not to use hides and bones from cows that were raised in countries where BSE has been found. The industry says that it's complying. Food companies also point out that much of the gelatin used to make desserts and candy comes from pig skins, not cow hides or bones.

C Vaccines are often made using cattle by-products that could be infectious. In 1993, the FDA asked vaccine manufacturers to stop importing animal products from countries where BSE has been found or where there isn't adequate surveillance for BSE. Last year, though, the government learned that five vaccine-makers hadn't complied.<sup>21</sup> It ordered them to do so.

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<sup>21</sup> U.S. FDA, Bovine Spongiform Encephalopathy (BSE), MMWR Notice to Readers: PHS Recommendations for the USE of Vaccines Manufactured with Bovine-Derived Materials, available at <<http://www.fda.gov/cber/bse/bse.htm>>Internet.

There is no evidence that any of the world's cases of variant Creutzfeldt-Jakob Disease were caused by contaminated vaccines, and the U.S. Public Health Service recommends that children and adults continue to be immunized.

C           Glandular dietary supplements are made from animal glands. Example: Rejuvex, which is marketed as a tonic for menopausal women, contains extracts from cow mammary, ovary, uterus, adrenal, and pituitary glands. But the uterus and adrenal gland of cattle with mad cow disease can contain infectious prions, according to the World Health Organization. So can the placenta and thymus, which are found in other supplements.

Supplement-makers say that they're complying with a 1993 FDA request that they not use cow organs from countries where BSE exists. Rejuvex labels, for example, say that its cow gland extracts come from "countries that are certified to be BSE-disease free." They are also planning to utilize a third-party auditing system to address the lack of FDA oversight.

The National Nutritional Foods Association, a trade group of 4,000 health food and supplement producers, distributors, and retailers, is urging its members to eliminate all cow neurological tissues from their dietary supplements.<sup>22</sup> But the FDA has no system in place to monitor what supplement companies actually put into their products.

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<sup>22</sup> Zwillich, Todd. "Group Says Cow Tissue in U.S. Supplements Risky," Reuters Health, March 19, 2001, available at <[http://dailynews.yahoo.com/h/nm/20010319/hl/supplements\\_madcow\\_1.html](http://dailynews.yahoo.com/h/nm/20010319/hl/supplements_madcow_1.html)>.